#7 Ex(2) Election/ Amdt B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Maertens et al

Serial No. **09/899,082**

Filed: **July 6, 2001**

For: **PROCESS FOR TYPING OF HCV ISOLATES**

Atty. Ref.: **2752-50**

Group: **1634**

Examiner: **WHISENANT**

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May 28, 2002

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

AMENDMENT

Responsive to the Office Action dated February 27, 2002, entry and consideration of the following amendments and remarks are requested, the period for response having been extended up to and including Tuesday, May 28, 2002, by submission of the requisite petition and fee, attached.

IN THE CLAIMS:

Amend the claims as follows:

B1

24. (Amended) A polynucleic acid selected from the group consisting of

CCC TGT GAG GAA CTW CTG TCT TCA CGC (SEQ ID NO 1),

GGT GCA CGG TCT ACG AGA CCT (SEQ ID NO 2),

TCT AGC CAT GGC GTT AGT RYG AGT GT (SEQ ID NO 3),

TTG GGC GYG CCC CCG C (SEQ ID NO 20), and

TCT GCG GAA CCG GTG A (SEQ ID NO 27),

or the complement thereof, wherein W represents A or T, R represents G or A, and Y represents T or C.

REMARKS

Reconsideration is requested.

Claims 24-45 are pending.

Responsive to the Official Action dated February 27, 2002, the applicants elect, with traverse, SEQ ID NO:1 for further prosecution in the above.

The restriction requirement should be withdrawn for any one or a combination of the following. An Action on the merits of all the claimed subject matter is requested.

The restriction requirement should be withdrawn as the Examiner has not sufficiently supported the Examiner's assertion that the claims present a burdensome search and/or are directed to separately patentable inventions. That is, the Examiner has not indicated by appropriate reliance on scientific or technical evidence that the separately claimed nucleic acid sequences are distinct, such as by showing the subject matter has attained recognition in the art as a separate subject for inventive effort and that a separate field of search is required, such as may be the basis for a restriction requirement pursuant to MPEP §808.02. In fact, the Examiner has admitted that the claimed subject matter has been classified by the Patent Office in the only two separate Classes and two Subclasses in each Class - which is submitted to be persuasive evidence that examination of all the claimed subject matter would not be an undue

burden on the Examiner. The undersigned submits examination of patent claims often require search of multiple Classes, without requiring an undue burden in searching.

In fact, the only reason for the restriction requirement appears to be the existence of multiple databases which require search. The applicants assume the databases are searched by a computer and, as the sequences have been submitted in electronic form, a search of these alleged multiple databases should be a matter of routine operation, likely conducted by an individual other than the Examiner.

The present application is a divisional of US Patent Application No. 09/378,900 which is a divisional of US Patent Application No. 09/044,665, now US Patent 6,051,696, which is a divisional of US Patent Application No. 08/256,568, now US Patent 5,846,704. These applications were examined by the present Examiner. A copy of the patent claims is attached for the Examiner's consideration.

The oligonucleotides with SEQ ID NO:1 and SEQ ID NO:2 are used in combination for the same purpose, i.e. amplification of (part of) the HCV 5' NCR. These sequences should be examined togther.

Claim 29 refers to a method for detecting the presence of an infection with HCV in a biological sample by means of hybridization with a polynucleotide with the sequence of SEQ ID NO 20 or 27 or the complement thereof used as an HCV specific probe. The Examiner is urged to appreciate that claim 1 of granted U.S. Patent No. 6,051,696 claims HCV-type specific probes consisting of one of SEQ ID NOs 5 to 54 or 93 to 96. The applicants submit that, pursuant to the PTO practice announced in the Commissioner's Notice published at 1184 OG 86 on March 26, 1996, method claims,

such as claims 29, 30 and 31, of the present application, may be allowed once allowable product claims are identified. As noted above, this Examiner has already indicated that SEQ ID NOs 5 to 54 and 93 to 96, are allowable such that the presently claimed methods, at least to the extent that they recite these sequences, should also be allowable, or at least require little to no search (i.e., examination should not be a burden) by the Examiner. Accordingly, the restriction requirement should be withdrawn.

Claim 32 pending in the current application refers to method for detecting the presence of an infection with an HCV virus in a biological sample by means of an amplification reaction using (a set of) primers that specifically hybridize to SEQ ID NOs 1-4 or the complement thereof. The Examiner is urged to appreciate that claims 9 and 11 of U.S. Patent No. 5,846,704 dependent on claim 1 of the same U.S. Patent which refers to a method of genotyping a HCV present in a biological sample comprising hybridization with a probe hybridizing to the region –291 to –66 of the 5'UTR region of HCV. Claim 9 of U.S. Patent No. 5,846,704 specifies that, before hybridization, the region -291 to -66 is amplified employing primers complementary to domains -341 to -171 and -67 to -1. In claim 11 of U.S. Patent No.5,846,704, these primers are specified as hybridizing to SEQ ID NOs 1-4 or the complements thereof. Thus U.S. Patent No. 5,846,704 describes a HCV genotyping method including an amplification step as described in pending claim 32 of the present application. Accordingly, similar subject matter has already been examined by the Patent Office and further examination of this related subject matter would not require an undue burden.

Furthermore, the applicants submit that HCV genotyping inherently includes HCV detection: genotyping is not possible without detection (whereas detection is possible without genotyping).

Claim 36 pending of the present application refers to a process for general amplification of the 5' UTR region of HCV isolates involving primers with SEQ ID NOs 2 or 4 and with primers degenerate with SEQ ID NOs 1 or 3, respectively. If a method for genotyping (or detection) of HCV is including an amplification step, this amplification should by definition be general.

The applicants respectfully submit that the restriction requirement is improper as imposing selection of a single SEQ ID NO places an undue burden on the applicants. More specifically, numerous sequences have, without being subject of a restriction/election requirement, been considered in co-pending US Patent Application No. 09/378,900 (copy of claims attached). The Examiner is requested to treat the related applications (and now patents) with consistency and examine all the presently claimed subject matter on the merits.

Finally, the applicants notes that the Examiner's restriction requirement would require filing **12** separate applications to pursue protection of the presently claimed invention. At the cost of approximately $700 per application, this is an inappropriate and unjustified expense to the applicant merely for filing to pursue protection for the claimed invention. In fact, the Examiner is requested to appreciate that for the invention disclosed in the International Patent Application PCT/EP93/03325, the applicants have already filed seven (7) U.S. patent applications (i.e., parent plus one continuation plus

five divisional applications); three (3) of which are now US Patents (US Patent 5,846,704; US Patent 6,051,696; and US Patent 6,171,784 - copies attached), and four (4) which are still pending (U.S. Patent Application No. 09/378,900; U.S. Patent Application No. 09/899,302; U.S. Patent Application No. 09/899,044 (copies of he claims of each are attached); and U.S. Patent Application No. 09/899,082 (i.e., the present application). The applicants have thus invested considerable amounts of time and resources in order to obtain protection of the disclosed invention. Moreover, the Patent Office has performed a number of searches on the disclosed invention, such that the applicants assume the Examiner is not required to repeat prior searches for each new application with related claims.

The applicants respectfully submit the Examiner has failed to follow the intent of the Commissioner's Notice published at 1192 OG 68 (November 19, 1996) as that Notice expressed an interest in striking a balance between the interests of the applicants and the Patent Office in advancing prosecution in an efficient manner ("to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR §1.141 *et seq.* and permit a reasonable number of such ... sequences to be claimed in a single application").

The Examiner's requirement that the prosecution of the present application be limited to one sequence places an undue burden on the applicants in seeking protection for their disclosed invention. That is, the Examiner's requirement shifts the burden to the applicants rather than striking the balance which is expressed in the Commissioner's

Notice. The search of the presently claimed invention places a reasonable burden on the Examiner and strikes the balance expressed in the Commissioner's Notice.

Withdrawal of the Restriction Requirement and examination of the pending claims are requested.

An early and favorable Action on the merits is requested.

The Examiner is requested to confirm, in his next Action, receipt of the certified copy of the priority documents and acknowledge the claim for foreign priority.

Return of an initialed copy of the PTO 1449 Form filed July 6, 2001, pursuant to MPEP § 609, with the Examiner's next communication, is requested.

Respectfully submitted,

NIXON & VANDERHYE P.C.

By: _____

B. J. Sadoff
Reg. No. **36,663**

1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100